

### DETAILED ACTION

1. Restriction requirement mailed on July 18, 2008 is vacated and time for reply is reset.

Claims 1-21 are currently pending in the instant application and are subject to a lack of unity requirement.

### *Election/Restrictions*

2. Restriction is required under 35 U.S.C. 121 and 372.

As written, claim 21 contains non-statutory subject matter. Refer to 35 U.S.C. 101:

*Inventions Patentable: Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.*

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous and widely divergent subject matter claimed, a precise listing of inventive groups cannot be made. The following groups are exemplary:

- I.     **Group I:**     Claims 1-19 drawn to products of the formula 1 wherein B is phenyl.
- II.    **Group II:**    Claims 1-19 drawn to products of the formula 1 wherein B is isoquinolinyl.
- III.   **Group III:**   Claims 1-19 drawn to products of the formula 1 wherein B is quinolinyl.
- IV.    **Group IV:**   Claims 1-19 drawn to products of the formula 1 wherein B is pyridinyl.

Art Unit: 1626

- V. Group V:** Claims 1-19 drawn to products of the formula 1 wherein B is benzothiophenyl.
- VI. Group VI:** Claims 1-19 drawn to products of the formula 1 wherein B is naphthyl.
- VII. Group VII:** Claims 1-19 drawn to products of the formula 1 wherein B is indolyl.
- VIII. Group VIII:** Claims 1-19 drawn to products of the formula 1 wherein B is naphthyloxy.
- IX. Group IX:** Claims 1-19 drawn to products of the formula 1 wherein B is a moiety other than in groups I-VIII above.
- X. Group X:** Claim 20 drawn to a method of using products of one of Groups (I-VIII). Please elect one group of patentably distinct compounds for which this method is to be examined.
- XI. Group XI:** Claim 21 drawn to the use of a caspase inhibitor.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

PCT Rule 13 which pertains to the Unity of Invention states that, "[t]he international application shall relate to one invention only or to *a* group of inventions so linked as to form a single general inventive concept." Furthermore, 37 CFR 1.475 part (b) states the following: "An

Art Unit: 1626

international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) *A* product and *a* process of use of said product; or...", emphasis added. Applicant's claims are drawn to **multiple** products (Groups I-IX) and **two** methods of using said products (Groups X-XI).

The claims, therefore, lack unity of invention.

Accordingly, Groups I-XI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical feature, the claims lack unity of invention and should be limited to only a product or a method of use. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

#### ***Election of Species***

3. As an additional requirement, with the election of any one of **Groups I-XI**, an election of species of a particular compound is also required. In order for this election to be considered fully responsive to this requirement the election **must include:**

#### **Groups I-XI:**

- a) the **name** and **structure** of the instantly claimed compound
- b) the **location** of the species (a) within the claims or (b) within the specification,

Art Unit: 1626

c) the **claims** that read on the elected species,

d) and a **definition** of the exact substitutions,

e.g. R<sub>1</sub> is Hydrogen, X is oxygen, etc...

**Group X:**

a single disease: a) inflammation or b) apoptosis

**Group XI:**

a single disease: a) inflammation or b) apoptosis

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

#### ***Inventorship Notice***

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

Art Unit: 1626

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samantha L. Shterengarts/  
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Application/Control Number: 10/568,503  
Art Unit: 1626

Page 8